

REMARKS

Claims 1, 3, 15, 29 and 41 have been amended. No new matter has been added. Support for the amendments may be found throughout the specification. Claims 2, 11-14 and 59-62 have been cancelled without prejudice. Applicants reserve the right to prosecute the subject-matter of these claims at a later date. New claims 68-77 have been added. No new matter has been added. Support for the new claims may be found at, for example, p. 19, line 24 to p. 35. line 17 and examples of the specification. Claims 37 and 38 have been withdrawn from consideration.

Claims 1, 3-10, 15-51, 63 and 68-77 are currently pending.

ELECTION/RESTRICTIONS

Applicants have withdrawn claims 37 and 38 from consideration in the claim set above. Applicants however, request the rejoinder of claims 37-39 if the pending claims are found allowable.

CLAIM REJECTIONS

Rejection under 35 U.S.C. § 101

The Examiner has maintained the rejection of claims 59-62 under 35 U.S.C. § 101 “because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process” See Office Action at p. 2. In an effort to expedite prosecution and not in acquiescence to any rejection, Applicants have cancelled claims 59-62 thus rendering this rejection moot with respect to those claims. Applicants respectfully request the withdrawal of this rejection.

Rejection under 35 U.S.C. § 112

The Examiner has maintained the rejection of claims 1 and 59-62 under 35 U.S.C. § 112, second paragraph as being indefinite. See Office Action at p. 3. In an effort to expedite prosecution and not in acquiescence to any rejection, Applicants have cancelled claims 59-62 thus rendering this rejection moot with respect to those claims.

With respect to claim 1, the Examiner contends that “claim 1 recites the broad recitation ‘an antimicrobial material,’ and the claim also recites ‘consists of nicin’ which is the narrower

statement of the range/limitation” and thus the claims are indefinite. See Office Action at p. 4. Not in acquiescence to the rejection but in an effort to expedite prosecution, Applicants have amended claim 1 such that the antimicrobial material is nisin. Applicants respectfully request reconsideration and withdrawal of all rejections under 35 U.S.C. § 112, second paragraph.

Rejection under 35 U.S.C. § 103

Sonnenberg

The Examiner has maintained the rejection of claims 1-11, 13-20, 22-36, 47-51, 59 and 61-63 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Publication No. 2002/0173436 to Sonnenberg et al. (“Sonnenberg”). See Office Action at p. 4. In an effort to expedite prosecution and not in acquiescence to the rejection, claims 2, 11, 13, 14, 59 and 61-62 have been cancelled thus rendering this rejection moot with respect to those claims. Claims 3-10, 15-20, 22-36, 47-51 and 63 depend from independent claim 1.

Claim 1 relates to a composition including (a) an antimicrobial material, and (b) an extract obtained from or obtainable from a plant of the Labiatae family, wherein (a) and (b) are different wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition.

Specifically, the Examiner has alleged that “[t]he reference does teach that each of the claimed ingredients is suitable for combination in an antimicrobial composition.” See Office Action at p. 4. The Examiner has further contended that since “[t]he reference clearly shows that the claimed ingredients were known to be used in equivalent fields of endeavor, ... it is considered obvious to combine them together.” See Office Action at p. 5.

Applicants traverse this rejection and respectfully maintain that the Examiner is incorrect in her analysis of Sonnenberg for the following reasons. Sonnenberg describes a process for making a multiphase soup with different sections or phases, which remains stable and *does* not split apart or break. See paragraphs [0012]-[0014] of Sonnenberg. Although Sonnenberg appears to refer to an antimicrobial composition in that it is concerned with soap, such antimicrobial action is of secondary importance. What is most relevant in Sonnenberg, and

which therefore would be considered by the person skilled in the art to be the over-riding teaching, is the ability of the soap to have more than one phase and remain intact over long periods of time. See for example, paragraphs [003]-[0014] of Sonnenberg. This is emphasized in the Summary of Invention, Sonnenberg states that

[t]he objects of the present invention were multiphase soaps in which the different phases may have different ingredients which, during use, have stability comparable with that of a single-phase soap. In particular, it is possible for the different phases to comprise different perfume oils so that, during use, different successive scent experiences are possible.

We have found multiphase soaps comprising two or more phases which are characterized in that the latter are highly visible when viewed from above and from the side.

The multiphase soaps according to the present invention exhibit superproportional strength, which virtually corresponds with the stability of a single-phase soap.

See paragraphs [0012]-[0014] of Sonnenberg.

While it is acknowledged that the technical area of a document is not of importance for the assessment of novelty, this is clearly not the case for obviousness here. The document should be in a field which is relevant to the subject matter of the claimed invention and its intended purpose. However, that is clearly not the case in Sonnenberg. What is most relevant in Sonnenberg, and which therefore would be considered by the person skilled in the art to be the over-riding teaching, is the ability of the soap to have more than one phase and to remain intact for over long periods of time. Thus, when seeking to produce a composition including an antimicrobial material, a person of skill in the art would not even be motivated to turn to Sonnenberg as this reference is of secondary or even lesser importance.

Secondly, and with regard to antimicrobial compositions, all that is disclosed in Sonnenberg are general teachings regarding soap ingredients. Thus, while the introduction of various additives into soap is discussed (see for example, paragraph [0052]), there is a large number of different additive "types" which a person skilled in the art could add to soap. Further, the list of different individual additive within each "type" is vast. Therefore, once the type of additive has been chosen, the person skilled in the art would then have to make another choice with regard to the specific additive.

Thirdly, there is no single embodiment disclosed in Sonnenberg which features all of the components of claim 1. Thus, there is no indication of any "general conditions," let alone

specific conditions or concentrations. As a result, the person skilled in the art cannot be considered to be able to perform routine optimization when the general conditions and even the original embodiment itself are absent from the prior art document.

Further, it is pointed out that a synergistic relationship exists between the components of the present claims. See p. 5, lines 17-21 of the specification. This can clearly be seen by looking at the examples of the present application. See p. 32-43 of the specification. A synergistic effect is not the obvious result of combining two ingredients. Amended claim 1 requires that the composition includes phenolic diterpenes in an amount of greater than 1.0 wt. %, carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. %. Thus, there are specific requirements for the components of the claims. By contrast, a skilled person, when seeking to "optimize" the teachings of Sonnenberg would clearly not come to the amounts seen in the present claims.

In summary, a skilled person would have to, when attempting to produce an antimicrobial composition which is suitable for use in foodstuffs:

- (i) turn to a document concerned with soap which does not mention food products anywhere; then
- (ii) choose, out of a long list of additives, to add an extract from a plant of the Labiatae family; then
- (iii) choose, out of an extremely long list of antimicrobials, to add nisin; then
- (iv) choose to only add the plant extract in an amount such that the amount of phenolic diterpene was greater than 1.0 wt%; then
- (v) choose to limit the amount of carvacrol and carvone in the composition.

The above-recited steps are clearly not routine in view of the synergistic effects displayed by the components of the presently claimed composition. As such, Sonnenberg does not teach or suggest a composition including (a) an antimicrobial material, and (b) an extract obtained from or obtainable from a plant of the Labiatae family, wherein (a) and (b) are different wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein when the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition.

Accordingly, since claims 3-10, 15-20, 22-36, 47-51 and 63 depend from independent claim 1, those claims are patentable over the Sonnenberg for at least the reasons described above. Applicants respectfully request reconsideration and withdrawal of this rejection.

Todd, Bard and King

The Examiner has maintained the rejection of claims 1-36, 39-51 and 59-63 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,084,923 to Todd Jr. ("Todd"), U.S. Patent No. 3,679,434 to Bard et al. ("Bard") and U.S. Patent No. 6,451,365 to King et al. ("King"). See Office Action at p. 5-6. In an effort to expedite prosecution and not in acquiescence to the rejection, claims 2, 11, 13, 14 and 59-62 have been cancelled thus rendering this rejection moot with respect to those claims. Claims 3-10, 12, 15-36, 39-51 and 63 depend from independent claim 1.

In particular, the Examiner has alleged that Todd teaches antimicrobial compositions that include, amongst other additives, rosemary extract. See Office Action at p. 6. The Examiner further alleges that Bard teaches the use of polyphosphates in antimicrobial compositions and that King teaches the use of amongst other additives, nisin in antimicrobial compositions. See Office Action at p. 7. The Examiner has further alleged that "an artisan of ordinary skill would reasonably expect that anti-oxidants, antimicrobials, agents to prevent rancidity could be used as the types of composition taught by the references." See Office Action at p. 6. While the Examiner has acknowledged that "[t]he references also do not specifically teaching adding the ingredients in the amounts claimed by applicant, [t]he amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize." *Id.* Applicants respectfully traverse this rejection.

Todd teaches anti-oxidant compositions which includes activated ascorbic acid as an antioxidant. See Abstract of Todd. Todd does not describe or mention antimicrobial compositions. Thus, despite the allegation by the Examiner that the above compositions are used for the same purpose, Todd is not concerned in any manner with providing an antimicrobial effect. As such, Todd would not be considered by the person skilled in the art as being suitable for producing a composition that includes an antimicrobial.

King is concerned with providing antimicrobial compositions that include nisin and hops acid extracts. See Abstract of King. Hops acids are chemically different from rosemary extracts and thus their method of action is also different. Hops acids provide an antimicrobial effect through the ability to diffuse across the cell membrane of a bacterium and disrupt the intracellular pH. The resulting disruption in pH affects the electron transfer and cell respiration of the bacterium. By contrast, rosemary extract is an anti-oxidant which does not have a similar effect. In fact, King does not mention that its compositions should have an anti-oxidant effect and anti-oxidants are not even referred to in King. Thus, it is clear that the compositions of Todd and King are used for entirely different purposes; Todd discloses anti-oxidant compositions, but does not mention anti-microbial compositions, whereas King discloses anti-microbial compositions, but does not mention anti-oxidant compositions. Applicants submit that a person of skill in the art would not look or be motivated to combine the teachings of Todd and King.

It is assumed that the Examiner has cited Bard for being allegedly relevant to the polyphosphates used *in the present* invention as chelating agents. However, for Bard to be relevant, a composition comprising an antimicrobial (nisin) and an extract from the member of the labiatae family (rosemary) must first be present. In view of the comments made above with regard to Todd and King, this is clearly not the case. Even if the person skilled in the art were to make the combination suggested by the Examiner (which Applicants submit that they would not), they would still have to provide the components in the specific concentrations featured in present claim 1. However, despite the allegations of the Examiner, such specific concentrations cannot simply be regarded as "routine optimization."

In order for the person skilled in the art to perform routine optimization on the amounts of specific components in a composition, the person skilled in the art must first know how much of each component is generally present, i.e. they must know the general conditions of the composition. However, in coming to the above conclusion, the Examiner has alleged that the phenolic diterpenes and triterpenes, ursolic acid and rosmarinic acid are all "intrinsically" present. If this is the case, no general amount of each component can be given because although they may be present, it is not known in what quantity. As a result, the person skilled in the art cannot be expected to perform routine optimization of the concentrations of specific components when no initial general concentration is disclosed.

Moreover, the synergistic effects displayed in the present claims could not be considered as an obvious result of combining the teachings of Todd and King. Therefore, even if the skilled person were to combine the references (which Applicants submit that they would not), the skilled person would not optimize the amounts as in the present claims as it would be expected that the concentrations of each component should be maximized and this is clearly not the case. For example, Table 2 on p. 36 of the specification clearly shows that the amounts of Rosemary extract and nisin do not have to be maximized to achieve the best effect on *Listeria* growth.

Still further, Todd, at col. 5, lines 56-61 teaches that when present, the Labiatae extract should be present in the composition in amount in about 4 to 10% by weight. According to the teachings at p. 13, lines 19-22 of the specification, such extracts are characterized by their high phenolic diterpene content, which is typically greater than 3.5 wt.%. Therefore, a composition having from 4 to 10 wt. % of such an extract (as described in Todd) would typically only have about 0.14 to 0.35 wt. % phenolic diterpene present. Indeed the extract disclosed in Todd is the rosemary extract Herbalox-O™. See col. 6, lines 52-54 of Todd. The phenolic diterpene content of Herbalox-O has been analyzed and has been found to be in the range of 4.2 to 4.3 %. Thus the compositions of Todd clearly require that the amount of phenolic diterpene in the range of 0.168 to 0.43%.

In contrast, claim 1 requires phenolic diterpenes in an amount of greater than 1.0 wt. % to be present in the composition. Therefore, the amount of phenolic diterpene in the present composition is at least twice as much as taught in Todd. Thus, to simply state that the skilled person would carry out "routine optimization" in order to reach the subject matter of the present claims disregards this clear teaching in Todd as well as the synergism displayed by the present invention.

As such, none of the above-cited references, alone or in combination, teach or suggest a composition including (a) an antimicrobial material, and (b) an extract obtained from or obtainable from a plant of the Labiatae family, wherein (a) and (b) are different wherein the composition contains phenolic diterpenes in an amount of greater than 1.0 wt. %, based on the composition, and wherein when the antimicrobial material consists of nisin, the composition includes carvacrol in an amount of less than 0.075 wt. % based on the composition and carvone in an amount of less than 15 wt. % based on the composition.

Accordingly, claim 1 and claims that depend therefrom, are patentable over the combination of Todd, Bard and King for at least the reasons described above. Applicants respectfully request reconsideration and withdrawal of this rejection.

Patentability of new claims 68-77

Claim 68 depends from independent claim 1. As previously discussed, none of the above-mentioned references teach or suggest a composition as described in claim 1. As such, claim 68 is patentable for at least the reasons described above.


Independent claim 69 relates to a foodstuff having a phenolic diterpene content of greater than, or about, 0.00084 % w/w and a nisin content of greater than, or about, 25 IU/ml or 25 IU/g. None of the above-cited references describe a foodstuff as disclosed in claim 69. As such, claim 69 and dependent claims 70-77 are patentable over the Sonnenburg, Todd, Bard and King references.

CONCLUSION

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. A Request for Continued Examination and petition for extension of time is attached. Applicants believe that the claims now pending are in condition for allowance. Applicants have added 60 new claims and cancelled 20 claims. Please charge \$2,000 to Deposit Account 19-4293 for the 40 new claims. Should any other fees be required by the present Amendment, the Commissioner is hereby authorized to charge Deposit Account **19-4293**.

Respectfully submitted,

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